

## REMARKS

The Official Action dated December 1, 2006 has been carefully considered. By the present amendment, independent claims 1 and 8 have been amended to add the recitation of "wherein the composition has a pH of from about 5 to about 9 and is formulated to achieve in situ generation of dioxirane." Support for this language is found throughout the instant specification, including, e.g., [0013], last sentence, [00015] first sentence, and [00023], first sentence. As this amendment does not include new matter, entry is believed in order and is therefore respectfully requested.

Claims 1, 2, 4, 8, 9, 11 and 29-52 are currently pending and subject to examination.

### 35 U.S.C. § 103(a)

Claims 1, 2, 4, 8, 9, 11 and 29-52 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,046,150 to Choy (hereafter "Choy") in view of U.S. Patent No. 5,403,549 to McNeil (hereafter "McNeil"). Specifically, the Examiner asserts that Choy teaches liquid cleaning or bleaching compositions comprising peroxygen sources such as monopersulfate, and surfactants, including ethoxylated phenols containing 8 to 16 carbon atoms and averaging 1.5 to 30 moles ethylene oxide per mole of alcohol. The Examiner further asserts that when the Choy compositions are used as hard surface cleaners, alkaline buffers may be used including "alkali metal carbonates." The Examiner considers the hard surfaces set forth in Choy as "within the scope of decontaminating materials contaminated with biological warfare agents." The Examiner states that solvents, including isopropanol, ketones, etc. may also be used in the compositions. The Examiner notes that Choy fails to teach "the use of acetone or a composition containing a monopersulfate compound, a carbonate or bicarbonate, a ketone, a cosolvent, and the other requisite components of the composition in the specific proportions as recited by the instant claims."

With respect to the secondary reference, the Examiner asserts that McNeil teaches a method and a composition for disinfecting matter or materials such as medical instruments, operating rooms, floors, etc. that have been contaminated with bacteria, bacterial spores, fungi or viruses. Specifically with respect to the composition, the Examiner asserts that the McNeil compositions contain "a fluid mixture containing a peroxy monosulfate salt and a carbonyl-containing compound and reaction products thereof," and that the carbonyl containing compound is particularly selected from the group consisting of acetone, 2-pentanone, 4-hydroxy-4-methyl-2-pentanone, etc. and that additionally, surfactants may be used in the compositions. Finally, the Examiner asserts that McNeil teaches that the use of a commercially available buffer does not interfere with the activity of the dioxirane containing reaction product, and that McNeil states in Example 2 that "mixing carate with a ketone in the presence of a small amount of buffer yielded no bacterial growth which is desirable."

The Examiner concludes that it "would have been obvious to one of ordinary skill in the art at the time the invention was made to use acetone in the composition taught by Choy with a reasonable expectation of success because McNeil teaches the use of acetone in a similar disinfecting, hard surface cleaning composition and because Choy teaches the use of ketones as solvents in general." The Examiner further concludes that it "would have been obvious to one of ordinary skill in the art...to decontaminate materials contaminated by viruses by using a composition containing a monopersulfate compound, a carbonate or bicarbonate, a ketone, a cosolvent and the other requisite components of the composition in the specific proportions as recited by the instant claims, with a reasonable expectation of success because the broad teachings of Choy, in

combination with McNeil, suggest decontaminating materials contaminated by viruses by using a composition containing a monopersulfate compound, a carbonate or bicarbonate, a ketone, a cosolvent, and the other requisite components of the composition in the specific proportions as recited by the instant claims.” This rejection is traversed and reconsideration is respectfully requested.

Instant independent claim 1 is directed to a novel composition comprising: water; one or more monopersulfate compounds; one or more buffers, at least one of which is selected from the group consisting of alkali metal and alkaline earth metal salt forms of bicarbonate and/or carbonate; one or more ketones, at least one of said ketones being selected from the group consisting of acetone, 2-butanone, 2-pentanone, 2-hydroxy-4-methyl-2-pentanone, hexafluoroacetone, trifluoroacetone, acetophenone, camphorsulfonic acid, and levulinic acid; and one or more co-solvents. The composition has a pH of from about 5 to about 9 and is **formulated to achieve in situ generation of dioxirane**.

Instant independent claim 8 is also directed to a novel composition comprising: water; one or more monopersulfate compounds; one or more buffers, at least one of which is selected from the group consisting of alkali metal and alkaline earth metal salt forms of bicarbonate and/or carbonate; one or more ketones, at least one of said ketones being selected from the group consisting of acetone, 2-butanone, 2-pentanone, 2-hydroxy-4-methyl-2-pentanone, hexafluoroacetone, trifluoroacetone, acetophenone, camphorsulfonic acid, and levulinic acid; and one or more surfactants. The composition has a pH of from about 5 to about 9 and is **formulated to achieve in situ generation of dioxirane**.

Choy, on the other hand, is directed to liquid cleaning/bleaching compositions containing certain novel N-alkyl ammonium acetonitrile compounds to provide stability and increase shelf life of compositions containing peroxyacid bleaching compounds in alkaline solutions (see generally, “Background of the Invention” and specifically column 2, lines 47-50 and column 3, lines 1-4). Choy discloses monopersulfates or the equivalent aqueous form, Caro’s acid, (peroxymonosulfuric acid, H<sub>2</sub>SO<sub>3</sub>) as a suitable active oxygen sources (column 5, lines 1-3 and lines 18-21).

Contrary to assertions by the Examiner, Choy does not teach hard surface cleaning compositions comprising ketone in a form that permits in situ generation of dioxirane. “Ketone,” as presently disclosed, is an integral ingredient to the present composition and is required, in combination with the monopersulfate ingredient, to achieve the requisite generation of dioxirane. In addition, the instantly inventive compositions must be formulated so that the ketone and monopersulfate achieve in situ generation of dioxirane.

With respect Choy’s broad teaching of a ketone ingredient, Applicants note that ketone is disclosed, for purposes of formulating the Choy compositions, as a solvent solely with respect to providing a suitable liquid medium for the inventive N-alkyl ammonium acetonitrile compounds (hereafter MMAs) (column 10). Choy teaches that the MMAs, “are” combined with a liquid medium, which may be water or water combined with solvents, and immediately thereafter lists “ketones” as one of solvents that may be suitable for this purpose.

Applicants further note that in order to achieve the presently requisite in situ generation of dioxirane, the monopersulfate reactant and the ketone reactant are, for example, kept separate until application, when blending occurs just prior to delivery through use of certain sprayer technology

known in the art. Clearly, in the circumstance when both a monopersulfate is selected as a peroxygen source, and ketone is selected as a solvent for the MMA ingredient, dioxirane, to the extent it is generated at all, is generated immediately unless the reactants are kept separated until application.

Applicants agree, however, that Choy does teach separate containment of certain ingredients with blending occurring at delivery specifically in the case of treatment of hard surfaces (column 11, first full paragraph). This containment is preferred in order to control pH, which is desirably acidic for storage of the MMA and alkaline for treating hard surfaces (id. at lines 9-10). Specifically, Choy teaches containment of the peroxy ingredient and MMA ingredient in one chamber, and the buffer and certain surfactants in another chamber (id.). Hence, Applicants submit that Choy's composition embodiments ultimately formulated for in situ application by this delivery system, are not capable of in situ generation of dioxirane, and this is true *even* if one considers and employs ketone as a solvent for the MMA, and monopersulfate as an oxygen source. Clearly, ketone, disclosed by Choy solely and expressly as a potential solvent for MMA, would be in the chamber with the monopersulfate and, therefore, any dioxirane generation would occur in that chamber, prior to blending and application. Applicants submit that Choy fails to teach any compositions, expressly or impliedly, intentionally or inadvertently, that achieve the in situ generation of dioxirane as required by both instant independent claims.

The asserted secondary reference, McNeil, fails to cure this deficiency in the primary reference. The teachings of McNeil are actually addressed by the applicants in the instant specification in paragraphs [00012] and [00015], where McNeil is distinguished from the present invention by its divergent teachings regarding pH and its narrow teachings regarding effective temperature.

The Examiner asserts McNeil specifically for its teachings of the particularly disclosed ketones presently recited as suitable for generation of dioxirane according to the present invention. However, assuming arguendo that the requisite motivation to combine even exists, inclusion of the specific McNeil ketones into the compositions of Choy still fail to achieve the in situ generation of dioxirane since the specific ketone would be contained with the monopersulfate ingredient resulting in the substantially pre-application generation rather than in situ generation of dioxirane, as required by the present claims.

Further, Applicants submit that McNeil teaches away from the present invention, because McNeil expressly teaches that dioxirane generation using ketone should take place in an acidic environment, and requires buffers only in compositions having an acidic pH range of about 4 as successful in achieving effective disinfection. In fact, McNeil expressly teaches against buffers in general in Example 1 at column 11, lines 23-25, stating that "addition of buffer inhibited the bactericidal activity of the mixture..." In example 2, the Example cited by the Examiner as underpinning a suggestion to add a buffer, McNeil actually shows that a very small amount of buffer (potassium phosphate) "yielded no bacterial growth," but that a higher concentration of buffer "inhibited the sporicidal activity..." In Example 4, also cited by the Examiner as evidencing a suggestion or motivation to include a buffer, McNeil expressly teaches that the "buffer interferes with bactericidal and sporicidal activity." The only instance wherein a "commercially available buffer" (potassium biphtalate according to footnote 5 of Table 4) is added with retention of at least some dioxirane activity is found in sample C-15N, however this composition is formulated at a very acidic pH (4) that would be corrosive to most materials. Hence, throughout the McNeil

specification, use of a buffering ingredient is expressly discouraged except in acidic and/or corrosive formulations, and McNeil fails to suggest or disclose the presently recited buffers at any pH.

The use of a carbonate-based buffer, as required by the present inventive compositions, represents a patentably distinguishing improvement over the compositions and methods of McNeil, which teaches that the dioxirane generation is inconsistent or unsuccessful in the presence of buffer within the 5 to 9 pH range and that acidic pH is required to effect desired sterilization in the presence of buffer. Inclusion of the requisite carbonic buffers in the dioxirane-generating composition confers at least three benefits over the prior art: (1) the instant inventive compositions achieve effective decontamination in a less acidic and therefore less corrosive pH range; (2) the instant inventive compositions achieve effective decontamination over a much broader temperature range; and (3) the by-products of the generation of dioxirane are substantially environmentally benign.

To establish prima facie obviousness of the claimed invention, all the claim limitations must be taught or suggested by the prior art, *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). Furthermore, references relied upon to support a rejection under 35 U.S.C. §103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public, *In re Payne*, 203 U.S.P.Q. 245 (CCPA 1979). The compositions of Choy fail to suggest or achieve the requisite in situ generation of dioxirane. McNeil's specific disclosure of acetone as a desirable ketone fails to cure this deficiency, as regardless of the identity of the Choy ketone, it is contained with the peroxygen (monopersulfate) source chamber. The combination of Choy and McNeil, therefore, fails to teach all the claim limitations of the instant independent claims. Further, the combination of Choy and McNeil fails to provide an enabling disclosure because they fail to achieve in situ generation of dioxirane. Finally, McNeil teaches away from the instantly claimed compositions by teaching away from buffers in all but highly acidic formulations. Neither reference teaches or suggests the inclusion of the presently requisite carbonic-based buffer in dioxirane-generating compositions, a combination which confers the substantial advantages to the present decontamination compositions over the prior art.

Hence, the rejection of independent claims 1 and 8 and claims 2, 4, 9, 11 and 29-52 under 35 U.S.C. § 103 as unpatentable over Choy in view of McNeil has been overcome. Reconsideration is respectfully requested.

### **Double Patenting.**

The examiner has re-iterated the rejection of claims 1, 2, 4, 6-9, 11-17 and 19-23, under the doctrine of obviousness-type double patenting as being unpatentable over claims 8-27 and 34-40 of co-pending application Serial No. 10/693,194. The applicant at this time has not provided a terminal disclaimer in this application, but will consider such a disclaimer in the event the claims in this application and the co-pending application are allowed, and in the form allowed would constitute obviousness-type double patenting.

**Conclusion.**

Applicants believe this is a thorough and comprehensive response to the rejections of claims 1, 2, 4, 8, 9, 11 and 29-52 under 35 U.S.C. § 103 set forth by the Examiner in the December 1, 2006 office action. Applicants respectfully submit that the present application is in condition for allowance. The Examiner is encouraged to contact the undersigned to resolve efficiently any formal matters or to discuss any aspects of the application or of this response. Otherwise, early notification of allowable subject matters is respectfully solicited.

Respectfully submitted,

DINSMORE & SHOHL, LLP

By: /Monika J. Hussell/  
Monika J. Hussell  
Registration No. 37,359

Dinsmore & Shohl LLP  
900 Lee Street, Suite 600  
Huntington Square  
Charleston, WV 25301  
Telephone: (304) 357-9924  
Facsimile: (304) 357-0919  
monika.hussell@dinslaw.com